

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

<p><b>YUMEI LI-BACHAR,</b></p> <p style="text-align: center;"><b>Plaintiff,</b></p> <p><b>vs.</b></p> <p><b>JOHNSON &amp; JOHNSON, ETHICON, INC., and ETHICON, LLC,</b></p> <p style="text-align: center;"><b>Defendants.</b></p>	<p>Case No. _____</p> <p><b>COMPLAINT AND JURY DEMAND</b></p>
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Plaintiff, Yumei Li-Bachar, by and through her undersigned attorneys,, and in support of her Complaint states as follows:

**I. STATEMENT REGARDING PREVIOUS ACTIONS**

A previous action was filed by Plaintiff against Defendants on July 1, 2015, in the United States District Court for the Southern District of West Virginia, bearing Civil Action No. 2:15-v-9043, related to *In Re: Ethicon Inc., Pelvic Repair System Products Liability Litigation* MDL No. 2327. That action was resolved pursuant to the Order attached at Exhibit 1 to this Complaint.

**II. PARTIES, JURISDICTION AND VENUE**

**A. Plaintiff**

1. Plaintiff is, and was, at all times relevant hereto, a resident of Michigan.
2. On May 31, 2007, Plaintiff underwent bladder suspension surgery at Hospital Hotel Dieu Grace Hospital in Windsor, Ontario relative to her pre-operative diagnosis for stress incontinence, and was implanted with Gynecare TVT transvaginal mesh, manufactured by Ethicon Inc.

3. On April 5, 2021, Plaintiff underwent revision surgery at the Mayo Clinic in Rochester, Minnesota, which involved dissection of mesh from the urethra where the mesh had eroded into the urethra.

**B. Defendants**

4. Defendant, Johnson & Johnson (“J&J”) is a corporation, and according to its website, the world’s largest and most diverse medical device, and diagnostic company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

5. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its’ pelvic floor repair products. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are “Business Units” including the “Ethicon Franchise.” The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies, which comprise the Ethicon Franchise, are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

6. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant J&J located in Somerville, New Jersey.

7. Defendant, Ethicon, LLC, is a wholly owned subsidiary of Defendant J&J and is located in San Lorenzo, Puerto Rico. Ethicon LLC was charged by J&J with the manufacture of Ethicon Inc.’s pelvic floor repair products. The LLC is a resident of Ireland because the residency of a limited liability company is determined solely by its’ members, who are residents of Ireland.

8. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Gynecare TVT and other pelvic mesh products (hereinafter collectively referred to as “Pelvic Mesh Products” or the “Products”). Defendants manufacture, market, advertise, promote and sell Pelvic Mesh Products worldwide. As a result of the coordinated activities of all Defendants named above, Plaintiff was implanted with a defective pelvic floor repair product.

9. Defendants had a legal duty to ensure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by doing so provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products. Furthermore, Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

### **C. Jurisdiction and Venue**

10. This action is a civil action of which this Court has original jurisdiction under 28 U.S.C. § 1332 because it is a civil action between citizens of different states and, given the grave injuries sustained by Plaintiff as outlined herein, the amount in controversy exceeds the sum or value of \$75,000, exclusive of costs and interest.

11. Venue is proper in this Court, pursuant to 28 U.S.C. § 1391, because Plaintiff was injured by Defendants’ product and subsequently was forced to have the product removed in Rochester, Minnesota, which is in this judicial district.

12. Further, Upon information and belief, Defendants are, and, at all relevant times, were, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, including in the State of Minnesota, either directly or indirectly through third parties or related entities, its products, including the transvaginal mesh implanted during Plaintiff's 2007 surgery. The Court has personal jurisdiction over the Defendants because the Defendants, individually and/or acting in concert, presently and during the time of Plaintiff's 2007 and 2021 surgery regularly did business in the State of Minnesota such that they reasonably would expect to have to defend themselves in a Minnesota court.

### **III. DEFENDANTS' PELVIC MESH PRODUCTS**

13. In or about October, 2002, Defendants began to manufacture, market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

14. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily POP and SUI. Prolene Mesh was derived from Defendants' Prolene mesh hernia product and was and is utilized in the treatment of medical conditions in the female pelvis, primarily POP and SUI. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

15. On or about January 1, 2005, without seeking FDA clearance, the Defendants began to market and sell a product known as the Prolift System, for the treatment of medical conditions in the female pelvis, primarily POP and SUI. The Prolift System was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift and/or Prolift System include by reference all variations.

16. On or about May, 2008, the Defendants began to market and sell a product known as Prolift+M System, for the treatment of medical conditions in the female pelvis, primarily POP and SUI. The Prolift+M System was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M and/or Prolift+M System include by reference all variations.

17. On or about March 2010, Defendants began to market and sell a product known as Prosima System, for the treatment of medical conditions in the female pelvis, primarily POP and SUI.

18. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple and significant variations including, but not limited to, the TVT, TVT-Obturator (TVT-O), TVT-SECUR (TVT-S), TVT Exact and TVT Abbrevio. All references to TVT include by reference all variations.

19. As stated above, the products known as Prolene Mesh, Gynemesh, Prolift, Prosima, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' "Pelvic Mesh Products" or the "Products."

20. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, sold and distributed by the Defendants, at all times relevant herein.

#### **IV. FACTUAL BACKGROUND**

21. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to the surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP SUI. Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to

correct POP and SUI. Today, Defendants sell pelvic mesh “kits” which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

22. Defendants’ Pelvic Mesh Products are targeted for women who suffer from POP and SUI as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

23. Moreover, these Pelvic Mesh Products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants’ Pelvic Mesh Products. This immune response promotes degradation of the polypropylene mesh as well as the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

24. At various times, Defendants sought and obtained Food and Drug Administration (“FDA”) clearance to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Pelvic Mesh Product and, thus, a formal review of the safety and efficacy of the Pelvic Mesh Products was never conducted with regard to the Products. In the case of the Prolift product, Defendants marketed and sold the product for human implantation for over two years without the necessary clearance under Section 510(k).

25. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and directly to patients as a safe effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

26. The Defendants have marketed and sold the Pelvic Mesh Products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the Pelvic Mesh Products. Defendants further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

27. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device, when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purposes and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic permanent injuries.

28. For example, Defendants described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Pelvic Mesh Products were

consistent with any surgical procedure of an implantable medical device and described such occurrences as “rare” and “small” when in fact Defendants knew or should have known that the complications were not “rare nor small” but common, permanent, and debilitating.

29. Contrary to Defendants representations and marketing to the medical community and to the patients themselves, the Defendants’ Pelvic Mesh Products have high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law. The Products’ defects include, but are not limited to, the following:

- a. The use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;
- b. The design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c. The procedure itself, which is part of the Pelvic Mesh Products, requires the physician to insert the device “blindly,” resulting in nerve damage and damage to other internal organs;
- d. Biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;
- e. The lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in mesh contraction, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;
- f. The use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;
- g. Degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;
- h. Particle loss and or “shedding” of the mesh both during implantation and following implantation that results in additional undesirable complications including an increased inflammatory response and a migration of those particles resulting in injury.

- i. The welding and heating of the mesh itself during the production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;
- j. The design of trocars, as devices to insert the Pelvic mesh Products into the vagina, are defective because the device requires tissue penetration in the nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries;
- k. The propensity of the mesh for “creep,” or to gradually elongate and deform when subject to prolonged tension inside the body;
- l. The propensity of the mesh to contract, retract, and/or shrink inside the body;
- m. The inelasticity of the mesh, causing them to be improperly matted to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and
- n. The creation of a non-atomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer’s instructions.

30. Upon information and belief, the Defendants have consistently underreported and withheld information about the propensity of Defendants’ Pelvic Mesh Products to fail and cause injury and complications and have misrepresented the efficacy and safety of the Pelvic Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

31. Defendants have further deliberately chosen to forego the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

32. Despite the chronic underreporting of adverse events associated with the Defendants’ Pelvic Mesh Products, the underreporting of events associated with similarity designed competitor products, and Defendants’ deliberately avoiding the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

33. On October 20, 2008, the Food and Drug Administration (“FDA”) issued a Public Health Notification that described over 1,000 complaints (otherwise known as “adverse events”) that had been reported over a three-year period relating to Pelvic Mesh Products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Products that are the subject of the notification.

34. On July 13, 2011, the FDA issued a Safety Communication: “UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse.” Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of “continuing serious concern” (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were “not rare.” These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

35. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh “does not improve symptomatic results or quality of life over traditional non mesh repair.” The FDA concluded that “a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications.

Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible.”

36. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use, or labeling.

37. In fact, at the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

38. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (“ACOG”) and the American Urogynecologic Society (“AUGS”) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh... Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

39. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

40. Defendants also knew or should have known that: (1) some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the Pelvic Mesh Products and their predecessor

and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

41. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, and the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into Plaintiff.

42. Defendants' Pelvic Mesh Products are also defective due to Defendants' failure to adequately warn Plaintiff, Plaintiff's physician and health care providers of risks and complications including, but not limited to, the following:

- a. The Products' propensities to contract, retract, and/or shrink inside the body;
- b. The Products' propensities for degradation, fragmentation and/or creep;
- c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- d. The Products' lack of porosity in preventing proper mating with the pelvic floor and vaginal region.
- e. The rate and manner of mesh erosion or extrusion;
- f. The risk of chronic inflammation resulting from the Products;
- g. The risk of chronic infections resulting from the Products;
- h. The risk of permanent vaginal or pelvic scarring as a result of the Products;
- i. The risk of permanent vaginal shortening as a result of the Products;
- j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;
- k. The need for corrective or revision surgery to adjust or remove the Products;
- l. The severity of complications that could arise as a result of implantation of the Products;
- m. The hazards associated with the Products;

- n. The Products' defect described herein;
- o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;
- p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;
- q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;
- r. Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- s. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- t. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and
- u. The fact that neither pelvic organ prolapse, nor stress urinary incontinence, are life threatening conditions, and that other options, including non-surgical options, were available and superior alternatives to the use of the Products.

43. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Pelvic Mesh Products.

44. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products. Therefore, in the event of a failure, injury, or complications, it is impossible to remove the Pelvic Mesh Products easily and safely.

45. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

46. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

47. Furthermore, the Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the sales of the Pelvic Mesh Products,

and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

48. The Pelvic Mesh Product implanted into the Plaintiff was in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

49. Plaintiff and Plaintiff's Physicians foreseeably used and implanted the Pelvic Mesh Products and did not misuse or alter the Pelvic Mesh Product in an unforeseeable manner.

50. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of the organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control, and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

51. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh Products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

52. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

53. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health safety and welfare of Plaintiff.

54. Defendants failed to undertake their duties to properly know the qualities of their Pelvic Mesh Products and in representations to Plaintiff and/or to Plaintiff's healthcare providers, and concealed and intentionally omitted the following material information:

- a. That the Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapsed;
- b. That the Pelvic Mesh Products were not as effective as other products and procedures available to treat incontinence and/or prolapsed;
- c. That the risk of adverse events with the Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;
- d. That the risk of adverse events with the Pelvic Mesh Products were not adequately tested and were known by Defendants;
- e. That the limited clinical testing revealed the Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
- f. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;
- g. That Defendants were aware of dangers in the Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
- h. That the Pelvic Mesh Products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;
- i. That patients needed to be monitored more regularly than usual while using the Pelvic Mesh Products and that in the event the Pelvic Mesh Products needed to be

removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;

- j. That the Pelvic Mesh Products were manufactured negligently;
- k. That the Pelvic Mesh Products were manufactured defectively; and
- l. That the Pelvic Mesh Products were designed negligently; and designed defectively

55. Defendants were under a duty to disclose to Plaintiff and Plaintiff's physicians, the defective nature of the Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

56. Defendants had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products.

57. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause the Plaintiff, Plaintiff's physicians, and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or mislead Plaintiff and Plaintiff's physicians into reliance and cause Plaintiff to have the Pelvic Mesh Products implanted into her body.

58. At the time these representations were made by Defendants, and at the time Plaintiff used the Pelvic mesh Products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

59. Defendants knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported inaccurate, or otherwise downplayed warnings.

60. In reliance upon these false representations, Plaintiff was induced to, and did use the Pelvic Mesh Products, thereby sustaining severe and permanent personal injuries and damages.

Defendants knew or had reason to know that Plaintiff and Plaintiff's physicians and other health care providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Products, as described in detail herein.

61. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. Further, Defendants misrepresented to the Plaintiff and to the Plaintiff's physicians that the Pelvic Mesh Products were more effective than other means of treatment for these conditions for which they were implanted. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

62. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

63. The information distributed to the public the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Pelvic Mesh Products.

64. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Pelvic Mesh products specifically, that

the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Pelvic Mesh products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

65. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

66. Defendants chose to over-promote the safety, efficacy, and benefits of the Pelvic Mesh Products instead.

67. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, Plaintiff and her physicians; to gain the confidence of the public, the medical community, Plaintiff and her physicians; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products and induce Plaintiff, her physicians, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Pelvic Mesh Products.

68. Upon information and belief, Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Pelvic Mesh Products did not present serious health risks.

69. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

70. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and Plaintiff's healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and request the Pelvic Mesh

Products, and caused her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

71. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of Pelvic Mesh Products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

72. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts of Defendants misrepresentations.

73. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products, Plaintiff would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

74. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

75. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic

foreign body invasion, dense adhesions, and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theatre for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

76. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

77. At all relevant times herein, Defendants continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

78. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

79. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products system including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement, and multiple surgeries for mesh removal.

80. The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health and safety.

81. At all times herein mentioned, the employees, agents, officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion

of the aforementioned Pelvic Mesh Products when they knew of the hazards and dangerous propensities of said Pelvic Mesh Products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

## **V. FRAUDULENT CONCEALMENT**

82. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

83. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing defects, Defendants continued to represent its Pelvic Mesh Products as safe for their intended use.

84. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Pelvic Mesh Products. Because of Defendants' concealment of the true character, quality and nature of their Pelvic Mesh Products, Defendants are estopped from relying on any statute of limitations defense.

85. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, Plaintiff's physicians, healthcare providers and the public.

86. Defendants' acts before during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or cause thereof.

87. Defendants' conduct, as described in the preceding paragraphs, amount to conduct purposely committed, which Defendants must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

88. Defendants' conduct, as described in the preceding paragraphs, also amounts to a continuing tort and continues up through and including the date of filing of Plaintiff's Complaint. Despite diligent investigation, including consultations with Plaintiff's medical providers, the nature and extent of Plaintiff's injuries and damages and their relationship to the Mesh Product was not truly discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable limitations period for filing Plaintiff's claims.

## **VI. CAUSES OF ACTION**

### **COUNT I: NEGLIGENCE**

89. The foregoing paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.'

90. At all times material hereto, Defendants had a duty to Plaintiff, to exercise reasonable and ordinary care in the manufacture, design, labeling, packaging, testing, instruction, warning, selling, marketing, distribution, and training related to its Pelvic Mesh Products.

91. Defendants breached their duty of care and were negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the Pelvic Mesh Products in one or more of the following respects:

- a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;
- b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;
- c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;
- d. Failing to use reasonable care in inspecting the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

- e. Failing to use reasonable care in training its employees and health care providers related to the use of the Products so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;
- f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA and the public as set forth herein of risks associated with the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted including Plaintiff;
- g. Failing to use reasonable care in marketing and promoting the Products, so as to avoid unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;
- h. In negligently and carelessly promoting the use of the Pelvic Mesh Products to physicians who had not received sufficient training to master the techniques necessary for implantation of the device into the Plaintiff;
- i. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing or selling the Pelvic Mesh Products.
- j. Failing to conduct post market vigilance, or surveillance, by:
  - i. Monitoring or acting on findings in the scientific and medical literature; and
  - ii. Monitoring or investigating and evaluating reports in the FDA adverse events databases for their potential significance for defendants' Pelvic Mesh Products.
- k. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:
  - i. Failing to report MDRs (Medical Device [adverse event] Reports); and
  - ii. Failing to investigate reports of serious adverse events.

92. As a direct and proximate result of Defendants' negligence, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

## **COUNT II: STRICT LIABILITY – FAILURE TO WARN**

93. The foregoing paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

94. At all times material hereto, Defendants had a duty to provide adequate and sufficient instructions concerning the proper use of the Mesh Product, as well as warnings of the risks and dangers associated with using the Mesh Product, to Plaintiff, Plaintiff's medical providers, and the FDA.

95. The Defendants failed to properly and adequately warn and instruct Plaintiff, her physicians and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products.

96. The Defendants failed to properly and adequately warn and instruct Plaintiff, her physicians and her health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products, given the Plaintiff's conditions and need for information.

97. The Defendants failed to properly and adequately warn and instruct the Plaintiff, her physicians, and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe effective procedure for removal of the Pelvic Mesh Products.

98. In addition, the Pelvic Mesh Products were defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

- a. The Products' propensities to contract, retract, and/or shrink inside the body;
- b. The Products' propensities for degradation, fragmentation, disintegration and/or creep;
- c. The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- d. The rate and manner of mesh erosion or extrusion;
- e. The risk of chronic inflammation resulting from the Products;
- f. The risk of chronic infections resulting from the Products;
- g. The risk of permanent vaginal or pelvic scarring as a result of the Products;
- h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

- i. The need for corrective or revision surgery to adjust or remove the Products;
- j. The severity of complications that could arise as a result of the implantation of the Products;
- k. The hazards associated with the Products;
- l. The Products' defects described herein;
- m. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;
- n. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;
- o. Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;
- p. Use of the products puts the patient at greater risk of requiring additional surgery than feasible alternatives;
- q. Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- r. Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

99. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

100. As a direct and proximate result of the Pelvic Mesh Products' aforementioned defects, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death.

101. The Defendants are strictly liable in tort to Plaintiff for their wrongful conduct.

### **COUNT III: FRAUDULENT CONCEALMENT**

102. Plaintiff incorporates by reference the foregoing paragraphs of this Complaint as if fully set forth herein.

103. Plaintiff brings this fraudulent concealment claim under the common law.

104. Throughout the relevant time period, Defendants knew that their Pelvic Mesh Products were defective and unreasonably unsafe for their intended purpose.

105. Defendants fraudulently concealed from and/or failed to disclose to or warn Plaintiff, their physicians and the medical community that their Pelvic Mesh Products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

106. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Products because:

- a. Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;
- b. Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and
- c. Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiff.

107. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

108. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that patients would request and purchase the Defendants' Pelvic Mesh Products, and that healthcare providers would dispense, prescribe and recommend the Defendants' Pelvic Mesh Products, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Pelvic Mesh Products.

109. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff' physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of the Defendants' Pelvic Mesh Products, and are subject to

the same liability to Plaintiff for Plaintiff's pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Defendants' Pelvic Mesh Products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendants therefore have liability for fraudulent concealment under all applicable law, including, *inter alia*, *Restatement (Second) of Torts* § 550 (1977).

110. As a proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium and economic damages.

#### **COUNT IV: DISCOVERY RULE AND TOLLING**

111. Plaintiff incorporates the foregoing paragraphs of this Complaint as if fully set forth herein.

112. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

113. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

114. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations

for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

115. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).'

116. The statute of limitations in this case is adjusted pursuant to Exhibit 1 to this Complaint.

## **VII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiff for past present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;
2. Restitution and disgorgement of profits;
3. Reasonable attorneys' fees;
4. The costs of these proceedings;
5. All ascertainable economic damages, including past and future loss of income and earning capacity;
6. Such other and further relief as this Court deems just and proper.

Date: February 24, 2002

Respectfully Submitted,  
**OLIVER LAW GROUP P.C.**

/s/ Alyson Oliver  
Alyson Oliver (MI State Bar No. P55020)  
1647 W. Big Beaver Rd.  
Troy, MI 48084  
T: (248) 327-6556  
F: (248) 436-3385  
E: [notifications@oliverlawgroup.com](mailto:notifications@oliverlawgroup.com)

/s/ Daniel E. Gustafson  
Daniel E. Gustafson (#202241)  
Karla M. Gluek (#238399)  
Amanda M. Martin (#0341691)  
**Gustafson Gluek PLLC**  
120 South Sixth Street, #2600  
Minneapolis, MN 55402  
T: (612) 333-8844  
F: (612) 339-6622  
E-mails: [dgustafson@gustafsongluek.com](mailto:dgustafson@gustafsongluek.com)  
[kgluek@gustafsongluek.com](mailto:kgluek@gustafsongluek.com)  
[awilliams@gustafsongluek.com](mailto:awilliams@gustafsongluek.com)

***COUNSEL FOR PLAINTIFF***